EXHIBIT B

Expert Report of Elizabeth Park, Pharm.D., APh

October 19, 2021

The City & County of San Francisco, et al. v. Purdue Pharma L.P., et al.
Case No. 3:18-cv-07591-CRB

I. Qualifications

Since 2017, I have served as the principal of Simplified Medicine, Inc., a consultancy I founded dedicated to pharmacy education and compliance assessment. Simplified Medicine performs on-site pharmacy regulatory audits and regulatory gap analyses for pharmacy clients. Through Simplified Medicine, I have performed over 1,000 regulatory consults. I routinely serve as a California Board of Pharmacy-approved independent pharmacist consultant reporting on individual and entity licentiates subject to a disciplinary action during probationary time periods.

I provide regular, continuing education lectures on topics related to regulatory compliance, professionalism, and policies and procedures. For example, at the California Pharmacists Association "Western Pharmacy Exchange" annual convention, I teach about pharmacy regulatory compliance to practicing pharmacists, pharmacists-in-charge, and pharmacy owners. Additionally, the California Pharmacists Association engages me to teach various subjects related to pharmacy regulatory compliance at its Pharmacy Law and Practice Conference.

I serve as adjunct faculty at both (1) University of the Pacific – Thomas J. Long School of Pharmacy and Health Sciences, and (2) the California Health Sciences University School of Pharmacy. At both institutions, I teach Pharmacy Law and Ethics to pharmacy students. At California Health Sciences, I am an Adjunct Assistant Professor of Pharmacy Practice and have also taught pharmacy students on topics related to evidence-based practice and psychiatric diseases through didactic lectures as well as on-site preceptorship within advanced pharmacy practice experience settings. To date, I have personally precepted about 70 pharmacy students in either their Advanced Practice Pharmacy Experience (APPE) or PGY-1 Residency, and continue to do so today.

I hold a Pharm. D. degree from Western University of Health Sciences. Following completion of my studies, I served as Chief Resident in the Geriatric Psychiatry pharmacy residency at Los Angeles Jewish Home of the Aging, Joyce Eisenberg-Keefer Medical Center, where I continue to serve as a regulatory consultant. I am licensed by the California Board of Pharmacy as both a Registered Pharmacist (RPh) and Advanced Practice Pharmacist (APh).

I am the immediate past Reference Chair for the California Pharmacists Association, and I have served as a member of its Reference Committee since 2016. I also served on the Policy Committee and other various governance task forces. I also serve in the Advisory Council within the Dean's Leadership Council at the Thomas J. Long School of Pharmacy.

I have served as an expert witness in more than 50 administrative and civil cases on pharmacy practice and compliance issues. These cases have typically involved the topics of pharmacist-in-charge strict liability, internal theft and diversion, fraud waste and abuse, PBM audits, unlawful drug take-backs, prescription drug inventory discrepancies, alcohol and drug impairment, unlawful prescription drug order processes, corresponding responsibility violations, and unprofessional conduct.

Please refer to my attached Curriculum Vitae (Appendix A) for more details.

II. Assignment

I have been asked to assess (1) whether Walgreens, through its policies and procedures applicable to its pharmacists in San Francisco, provided them with the training and tools necessary to fulfill their corresponding responsibility in dispensing controlled substances prescriptions to the general public under the standard of pharmacy practice in California; and (2) whether the due diligence records Walgreens produced in this litigation demonstrate that its pharmacists fulfilled their corresponding responsibility and cleared red flags indicative of potential drug diversion.

III. Summary of Opinions

If called to testify at trial, I intend to offer the following opinions, which I hold to a reasonable degree of professional certainty:

1. The standard of practice for pharmacy in California places a corresponding responsibility on pharmacies and pharmacists to ensure that each prescription for a controlled substance is dispensed for a legitimate medical purpose.

2. The standard of practice for pharmacy in California requires a pharmacist to resolve and document resolution of every "red flag" of diversion presented by a prescription for a controlled substance before dispensing to the general public.

3. The standard of practice for pharmacy in California requires pharmacies to implement, audit, and enforce policies, procedures, and systems that enable pharmacists to resolve and document resolution of red flags of diversion before dispensing to the general public.

4. A reasonable California pharmacist would recognize Red Flags Nos. 1 through 16, as defined in the expert report of Dr. Craig McCann on the basis of the expert report of Carmen Catizone, as red flags of diversion.

5. Walgreens' policies, procedures, and systems were too vague, ambiguous, and indefinite to guide its pharmacies and pharmacists in fulfilling their corresponding responsibilities under the California standard of practice.

6. Walgreens' performance metrics undermined its pharmacies' and pharmacists' compliance with their corresponding responsibility obligations under the California standard of practice.

7. Walgreens designed a disjointed and fractured system for recording due diligence with respect to resolving red flags, which does not appear to effectively convey such information from one pharmacist to the next and which does not meet the standard of practice in California.

8. Walgreens' efforts to audit and enforce compliance with its policies, procedures, and systems fell below the California standard of practice.

9. In a sample of approximately 2,300 prescriptions I reviewed, Walgreens pharmacies failed to resolve and document resolution of red flags more than 95% percent of the time.

Detailed statements of these opinions and their bases follow below.

IV. Materials Considered

My opinions in this report are based on my education, knowledge, experience, expertise, training, and on my review of the documents and information listed in Appendix B (Materials Considered). Included among those documents are Walgreens' policy and procedure documents. A substantial focus of my work in this case has involved reviewing the electronic and hard copy records Walgreens produced for approximately 2,300 prescriptions for which it represented that it had provided to Plaintiff a complete universe of due diligence documentation.

V. Red Flags of Diversion Under the California Standard of Practice[1]

According to California Health and Safety Code section 11153, "a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice."[2] While physician prescribers are responsible for ensuring this requirement is satisfied, a "corresponding responsibility rests with the pharmacist who fills the prescription."[3] The California Board of Pharmacy holds pharmacies accountable for their pharmacists' failure to fulfill their corresponding responsibilities.[4]

One element of the corresponding responsibility is to resolve and document resolution of "red flags" of diversion, or warning signs suggesting a controlled substance prescription was not issued for a legitimate medical purpose. Red flags require the pharmacist and pharmacy to conduct a reasonable inquiry to confirm the prescription is legitimate before the prescription may be filled. In 2013, in *Pacifica Pharmacy*,[5] the California Board of Pharmacy explained that (1) pharmacists must know and be able to recognize these red flags; and (2) in the presence of even one red flag, the pharmacist must perform a reasonable inquiry to resolve that red flag before filling the prescription. *Pacifica* reiterated what had long been the standard of practice in

[1] My opinions in this and subsequent sections are generally limited to the standard of practice for the dispensing of controlled substances in chain and retail pharmacies. I do not opine about dispensing in hospitals, skilled nursing facilities, and other institutional settings (like correctional facilities).

[2] Cal. Health & Safety Code § 11153.

[3] *Id.*

[4] *See generally* https://www.pharmacy.ca.gov/enforcement/discipline.shtml.

[5] *In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*. Board of Pharmacy Case No. 3802; OAH No. 2011010644; Precedential Decision No. 2013-01. Made precedential by the Board of Pharmacy effective August 9, 2013. https://www.pharmacy.ca.gov/enforcement/fy1011/ac103802.pdf.

California. For example, in the July 2001 edition of the Board's periodical, "The Script,"[6] the Board set forth specific questions and information that all pharmacists should ask, be aware of, and determine for themselves, before dispensing any controlled substance to the general public. Historical enforcement actions from the California Board of Pharmacy clearly show that corresponding responsibility and red flag analyses are required by all pharmacies and pharmacists, and that "red flags" are not a novel concept.

Every single red flag of diversion must be resolved before a prescription is dispensed. If a reasonable inquiry resolves every red flag (and that resolution is sufficiently documented), then the controlled substance prescription must be dispensed, pursuant to California Business & Professions Code § 733(a). If even one red flag is unresolved, then the controlled substance prescription order must not be dispensed, pursuant to California Code of Regulations Title 16 § 1761(b) and California Business & Professions Code §§ 733(a)(1) and 4330(b).

To be clear, the mere presence of any red flag does not mean that the prescription is unlawful or that the pharmacist should automatically decline to dispense it. Rather, the presence of a red flag triggers the duty to perform a reasonable inquiry, after which the pharmacist must decide to dispense or not dispense based on whether every red flag has been cleared.

Resolution of red flags must be documented. Pharmacists and pharmacies fall below the standard of practice and fail to meet their corresponding responsibility if they do not document: (1) the existence of red flags, (2) the ensuing reasonable inquiry, and (3) the final resolution of every red flag. One purpose of documentation is to ensure that both future pharmacists attending to the patient and regulatory authorities may be able to ascertain how the red flags were resolved. In my experience as an expert witness in Board of Pharmacy Accusations, pharmacies are required to provide documentation to corroborate *exactly how* any given red flag was resolved. Absence of this corroborating documentation equates to subjective assessment, which is not enough to resolve a red flag. Dispensing a controlled substance prescription after having conducted a reasonable inquiry and having resolved every red flag, but without adequate documentation, is unacceptable and falls below the standard of practice for pharmacies in California.

Reviewing a patient's history, including documentation of previous red flag resolution, can be helpful in conducting a reasonable inquiry if it is readily accessible to the pharmacist. However, prior documentation, even in the context of a patient's identical prior prescription, cannot relieve the pharmacist from their responsibility to independently identify, resolve, and document the resolution of any red flags presenting on the current controlled substance prescription. Generally, prior red flag resolutions are insufficient, by themselves, to resolve current red flags presented by the same patient. If consulting a patient history informs a pharmacist's reasonable inquiry, that fact must be documented.

Walgreens' own policies confirm the importance of proper and consistent documentation.

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[6] *Physicians and pharmacists have corresponding responsibility when writing and dispensing controlled substance prescriptions*. The Script, Page 3. https://www.pharmacy.ca.gov/publications/01_jul_script.pdf.

caregiver.[20] I have seen no evidence that Walgreens provided such guidance to its pharmacists.

O. Red Flag No. 15: Excess Days' Supply

I agree this scenario raises a red flag. The California Board of Pharmacy identifies prescriptions for duplicative therapy or prescriptions for unusually high quantities as red flags.

P. Red Flag No. 16: Cash Payment

I agree this scenario raises a red flag. The California Board of Pharmacy also specifically identifies cash payment for a controlled substance prescription as a red flag. This is one of the easiest and most frequently seen red flags that warrants a reasonable inquiry by the pharmacist.

For those patients for whom cash payments are a legitimate option, the pharmacy must require that the pharmacist document the facts and circumstances to resolve this red flag. Common and acceptable reasons for cash payment include: the patient cannot afford the insurance and has been unable to access public assistance (Medi-Cal); the patient is in-between carriers of health insurance; the patient has recently settled a worker's compensation case; and the patient's new employer requires a waiting period only after which health insurance is offered. Also, there may be unusual reasons for lack of coverage imposed by the insurance itself. The pharmacist must be given adequate staffing and time to contact the insurance provider for documentation or to determine coverage limitations. It is best practice in situations where the insurance provider has denied coverage for the pharmacist to then print the reasons for the denial and keep it in the patient file in a readily retrievable form, or else this information typically disappears if the same claim is covered at a later date.

Pharmacies should clarify within their policies and procedures that cash payments are a red flag that require a reasonable inquiry. Also, the policies and procedures should guide pharmacists on how to resolve this red flag, in that pharmacists must not only speak with the patient, but also contact the prescriber to confirm the legitimacy of the prescription itself, to discuss other medications that the patient is taking, and to request for documentation of a patient's underlying medical condition. Most importantly, the policies and procedures should require that the pharmacist ask the prescriber how the patient paid for their physician visits. Any such conversations and red flag resolution must be properly documented in detail.

VII. Walgreens' Policies, Procedures, and Systems Frustrated Its Pharmacies' and Pharmacists' Efforts to Fulfill Their Corresponding Responsibilities

I have reviewed a number of Walgreens' documents describing its policies, procedures, and systems relating to the dispensing of controlled substances. I have also reviewed the expert report of Carmen Catizone submitted in this case and his analysis of the same documents. All retail pharmacies, both small independent pharmacies and large nationwide chain drugstores, should implement proactive measures towards regulatory compliance that include pharmacy-provided training, adequate tools to be able to comply, and adequate time within the pharmacy

[20] https://meridian.allenpress.com/jcphp/article/65/1/42/441271/How-Do-You-Respond-to-Corresponding-Responsibility.

workflow to document the resolution of (or the failure to resolve) every red flag of diversion for each controlled substance prescription. Walgreens' policies failed to do so.

First, Walgreens' policies, procedures, and systems were too vague, ambiguous, and indefinite to guide its pharmacies and pharmacists in fulfilling their corresponding responsibilities. Walgreens' policies and procedures lack sufficient clarity, concreteness, guidance documents, and reference tools on dispensing controlled substances. Some policy provisions appear to discourage pharmacists from fulfilling their corresponding responsibility. Walgreens also does not appear to use its policies and procedures as working documents to be adjusted based on experiences and audits of work products. Policies and procedures are meant to ensure transparency, to communicate consistency, to eliminate operational confusion, and to ensure accuracy/quality of prescription drug dispensing to the general public. It falls below the standard of practice for Walgreens to provide vague and detail-poor policies and procedures and then rarely audit for actual compliance and performance of them (as described further below), thereby rendering the policies and procedures hollow and ineffective.

Below are some examples of Walgreens' insufficient and sub-standard of practice policies, procedures, and practices.

1. California Business & Professions Code § 4060 requires a pharmacy to ensure that the prescriber is prescribing within their scope of practice, and acting in the regular practice of the person's profession. But Walgreens' policies and procedures lack any meaningful criteria as to what this means, or how to implement this legal requirement. This is critical for pharmacies' and pharmacists' understanding of their corresponding responsibility.

2. Walgreens' policies and procedures lacked substance on how its pharmacists should exercise their corresponding responsibility by using the pharmacy's software, workflow, communication technology, or other pharmacy systems.

3. Walgreens' procedures for prescription validation[21] were deficient. When authenticating the patient's identification using a driver's license, the pharmacy must somehow document the existence of state-specific security features, so that pharmacy staff can rely on this as a guidance tool when verifying patient ID.[22] For most retail pharmacies it is common practice to use a UV light to check the ID's security features. Walgreens' policies and procedures failed to detail specifications when authenticating the patient's identification card.

4. When determining whether a prescriber has authority to prescribe certain types and doses of controlled substances, simply verifying the existence of the prescriber's DEA number and state license number—which is all Walgreens' policies provide

[21] WAGMDL00742666 at 66.

[22] This does not mean that specific types of identification are necessary to fill all prescriptions at all times. But pharmacies should have the proper equipment and training to validate identification and should be prepared to investigate and resolve any flags associated with missing or irregular identification.

for[23]—is insufficient. Reasonable pharmacy policies should also require confirmation that the prescriber is not on the Board of Pharmacy's "Prescribers with Restricted Authority to Prescribe Controlled Substances" lists, which are published regularly via email listserv to all pharmacies and pharmacists. The Board requires pharmacies and pharmacists to always keep their current e-mail addresses on file with the Board, which sends these lists routinely. Reasonable pharmacy policies should also require pharmacists to check if prescribers are found on the OIG Exclusions List or Medi-Cal's Suspended and Ineligible Providers List. The Board holds pharmacies and pharmacists responsible if they do not use these tools prior to dispensing controlled substance prescriptions. But Walgreens' policies and procedures make no mention of these resources.

5. When assessing a prescription, reasonable pharmacy policies provide a roadmap on how and when to use the CURES database. The best practice is to instruct pharmacists to generate a report with all addresses displayed for the patient as a result of a search, to check the date of last dispensing for the same medication, and to look for patterns of multiple prescribers, multiple pharmacies, and clinically problematic histories. The reports should also generally be printed, signed, and attached to the prescriptions or otherwise filed in an accessible location. Walgreens' Target Drug Good Faith Dispensing Checklist referenced CURES, but I found no explanation in the materials I reviewed of how pharmacists were supposed to use this tool as a reasonable pharmacist would.

6. According to Walgreens' presentation on "Prospective [DUR] at the Retail Setting,"[24] "any DURs that have a severity of Major" will automatically pop up a documentation screen where the pharmacist will then need to choose from the options from the drop-down menu—choosing either "Patient Consulted," "Prescriber Consulted," or "Reviewed Patient History," with the option to insert a written comment regarding that specific DUR. It falls below the standard of practice that, in the event that the program identifies an issue severe enough for pharmacist review, it would be optional (as opposed to mandatory) for the pharmacist to write a comment. The very fact that a comment is optional discourages pharmacists from doing so, as the drop-down window options create a false sense of security. If the patient or prescriber were consulted, what was discussed regarding the red flag that prompted the drop-down choice in the first place? If patient history was reviewed, then what was the purpose of that review, and what was the outcome? Reasonable pharmacists ask these questions, but Walgreens' policies do not—and, critically, do not require or sufficiently encourage pharmacists to document the answers.

7. Walgreens' Target Drug Good Faith Dispensing Checklist is grossly deficient. Substantively, it applies only to three single-ingredient opioids, which is

[23] WAGMDL00742666 at 66.

[24] WAGMDL00987026 at 29–82.

Year	TD GFD Completion Rate	Checklists produced for these prescription numbers[33]	Prescriptions requiring TD GFD checklists
2018	77.8%	8,067	10,367
2019	59.0%	5,285	8,954

X. Walgreens Pharmacies Failed to Resolve and Document Resolution of Red Flags of Diversion

I understand that Walgreens provided what it represented to be all documentation of any due diligence for approximately 2,300 prescriptions—all of which were subject to at least one of the 16 red flags discussed above—filled at 12 Walgreens locations in San Francisco over a ten-year period. The full universe of electronic notes, as I understand it, was to include all relevant electronic notes, TD GFD Checklists, hard copy prescriptions, and any other documents attached thereto (e.g., CURES reports). Dr. McCann organized the information and documentation received from Walgreens, which was relayed to me. I, along with staff working under my supervision, reviewed the dispensing data fields with respect to each of these prescriptions and confirmed independently—to the extent possible using the data available to me associated with the 2,300 prescriptions—that for each and every one, at least one of the 16 red flags was triggered.

For the 2,300 prescriptions, my staff and I reviewed all of the electronic notes fields, TD GFD checklists, hard copy prescriptions, and any other documents attached thereto to determine whether the red flags we identified had been cleared. This was a time-intensive process that required careful review of a significant amount of data. That analysis exposed Walgreens' systematic failure to consistently identify and investigate red flags and document the resolution thereof. Of the approximately 2,300 prescriptions, ***fewer than 5%*** contained evidence of due diligence that met the standard of practice or that a reasonable pharmacist in California would consider adequate to resolve the flag (or flags) identified. In other words, on this record, pharmacists properly implementing their corresponding responsibility in California should not have dispensed 95% or more of the prescriptions.

It is worth noting that, in most cases, Walgreens' electronic notes provide little to no information that any reasonable pharmacist or pharmacy would interpret as documentation that red flags were identified or resolved. Indeed, although Walgreens' dispensing software included more than thirty fields which Walgreens states could have been used to document due diligence resolution, those fields were sparsely populated, and where they were populated the content was either irrelevant or insufficient the vast majority of the time. For example, the "Annotation Text" field, which appears to have been a field that pharmacists at least occasionally used to document relevant information (e.g., "cures checked"), is blank 89% of the time. Of the 11% of prescriptions that do contain text in this field, nearly a quarter simply noted patient requests for a brand name drug. The "Patient comments" field, another place one might expect to find due diligence notes, was blank 86% of the time, and of the 319 prescriptions for which it was populated, 268 (84%) included nothing more than the patient's email address. The "Prescription_request_comment" field was populated 1,465 times, but approximately 1,200 of

those populated fields were limited to pre-supplied text indicating that a consultation was required. Of these prescriptions for which a consultation was apparently required, a third indicate that the consultation did *not* occur—yet the prescriptions were dispensed anyway. Even where the "prescription_resolve_comment" was populated, the majority consist only of auto-populated text. None of this is sufficient to demonstrate that relevant red flags were identified or resolved.

Relatedly, Dr. McCann calculated the number of times (and percentage of the time) that Walgreens' pharmacists populated each of the dozens of electronic fields that Walgreens contends could contain evidence of due diligence in the resolution of a red flag on an opioid prescription. Those calculations, which I understand will be included in Dr. McCann's supplemental report, further confirm both that the Walgreens system for recording due diligence was disjointed and sub-standard, and also that its pharmacists did not document red flag resolution in any meaningful or consistent way.

Even more shockingly, within the 2,300 prescriptions I carefully reviewed, there were many examples in which the notes actually made clear that the red flag was not only unresolved, but that it was in fact substantiated—and yet the prescription was dispensed anyway.

As a few examples, the following comments—all of which appear to confirm red flags and, in some cases, near-conclusive indications of illegitimacy—appear in the records for prescriptions that Walgreens filled:

- "Beware his patient is filling Oxycontin cash rx of thousands of dollars."
- "Possible Stolen Control Pads!!!"
- "Fraudulent call – ins 8/22/15 weekend, need to verify."
- "Overprescribes prometh/codeine: MD not cooperative with GFD requirements for this"
- "Phoney called in controls watch phone controls."

As discussed above, red flags typically cannot be resolved merely by reference to resolutions documented on past prescriptions, but if past documentation does inform resolution of a current red flag, that fact must be documented in the notes for the current prescription. I saw no such notes in my review of the approximately 2,300 prescriptions. Nevertheless, I reviewed the "patient history" for a randomly selected sample of 25 prescriptions within the 2,300—a spot-checking procedure I commonly employ in my practice as a pharmacy compliance consultant. That is, for each of those prescriptions, I reviewed all dispensing data and due diligence documentation produced by Walgreens for all prior prescriptions filled for the patient at issue in the set of 25 prescriptions. My analysis showed that the documented due diligence in the patient history of prior prescriptions would have resolved just *one* additional red flag in *one* prescription, for which two other red flags still were not resolved.

XI. CONCLUSION

Walgreens did not provide adequate tools and opportunities for its pharmacists to fulfill their corresponding responsibilities. My analysis showed that Walgreens pharmacists failed to fulfill their corresponding responsibility by resolving and documenting resolution of red flags of diversion in the overwhelming majority of the prescriptions I reviewed.

Respectfully submitted,

DocuSigned by:
Elizabeth Park
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Elizabeth Park, Pharm.D., APh

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